

REMARKS

I. Status of the claims

After entering this amendment, claims 25-65 and 67-73 will be pending.

Claim 66 has been cancelled without prejudice or disclaimer. Claims 62, 68, and 70 are being amended in this response. Support for the amendment of claim 62 can be found in the specification at p. 6, lines 3-9. Support for the amendment of claim 68 can be found in the specification at p. 11, lines 24-29. Support for the amendment of claim 70 can be found in the specification at p. 4-6 and Examples 1-4. Applicant acknowledges the allowance of claims 25-58.

Accordingly, all claims amendments find proper support in the specification and, therefore, no issue of new matter is being raised.

II. Rejections under 35 U.S.C. § 112, first paragraph

Claims 59-68 and 70-73

The Office rejected claims 59-68 and 70-73 under 35 U.S.C. 112, first paragraph, as allegedly failing to comply with the written description requirement.

The Office argues that claims 59, 63, and 64 omit the limitation that the formulations contain a calcium salt. The Office Argues that “it appears that every reference to the formulation and the examples for making the formulation all contain calcium salts and the Specification does not teach that the calcium salts may be omitted from the formulation of the invention.” Office Action at p. ¶ bridging pages 2-3.

Applicant respectfully traverses this rejection. Example 4 in the specification indicates that a thrombin granulate “mixed well with the fibrinogen granulate [e.g., from

Example 1] and was also suitable for use as fibrin adhesive.” Specification at p. 15, lines 18-19. Neither the thrombin granulate nor the fibrinogen granulate described therein contain calcium (contrast the preparation of the granulates in Examples 1 and 4 with the preparation of a fibrin adhesive granulate in Example 3, where the presence of calcium is explicit). Additionally, the specification also discloses at least another example of a preparation containing only fibrinogen and thrombin, without mentioning the need of a calcium salt. Specification at p. 11, lines 1-5. Therefore, the specification indicates that a fibrin adhesive lacking calcium was contemplated as part of the present invention. Accordingly, Applicant respectfully requests that this rejection be withdrawn.

Claim 62

The Office rejected claim 62 alleging that the specification does not support the claimed genus of water-soluble sugars, sugar substitutes, and biological transport substitutes. Applicant respectfully traverses this rejection because the skilled artisan, reading page 6, lines 3-9, and the specification as a whole, would surmise that the Applicant was in possession of fibrin tissue adhesive granulates wherein the support medium is selected from water-soluble sugars, sugar substitutes, biological transport substances. However, in an effort to expedite prosecution, Applicant has amended claim 62 to indicate that the support medium is selected from sugars, sugar alcohols, proteins, and mixtures thereof. Support for this amendment is found at p. 6, lines 3-9. Therefore, this rejection is now moot and Applicant respectfully requests that the rejection be withdrawn.

Claim 68

The Office rejected claim 68 alleging that the specification does not appear to disclose that the granulates are provided with an outer barrier layer. Applicant respectfully traverses this rejection. Examples 6 to 8 clearly disclose that the fibrin adhesive granulates of the invention are covered with a solution of isoproanol/PEG. The specification explains that the use of an “organic solvent [such as isoproanol] is excellent suited for *the coating* because it evaporates easily, *prevents a reaction with fibrin and ensures that the activity of the individual components is maintained.*” Specification at p. 11, lines 24-27, emphasis added. Moreover, the specification adds that “the granulate form is maintained after treatment in the organic solvent.” Specification at p. 11, lines 28-29. This disclosure indicates that the isoproanol/PEG coating solution acts as an outer barrier layer. However, in order to more clearly define the scope of the claim, Applicant amended claim 68 to indicate that the granules are “covered” with an outer barrier layer. Because the specification supports the subject matter of claim 68, Applicant respectfully requests that this rejection be withdrawn.

Claims 70-73

The Office rejected claims 70-73 alleging that the temperature range limitation present in these claims (“temperature not exceeding 50°C”) is not disclosed in the specification. Without acquiescing to this rejection, Applicant has amended independent claim 70 (from which claims 71-73 depend) deleting the phrase “temperature not exceeding 50°C.” Therefore, this rejection is now moot and Applicant respectfully requests that the rejection be withdrawn.

III. Rejections under 35 U.S.C. §135(b)

The Office rejected claims 59-73 under 35 U.S.C. §135(b) arguing that the claims were not “made prior to one year from the date on which [U.S. Application Publication No.] 2002/0037323 was published.” Office Action at p. 4. Applicant respectfully traverses this rejection.

35 U.S.C. §135(b) is not applicable to the present case. Section 135(b)(2), states:

A claim which is the same as, or for the same or substantially the same subject matter as, a claim of an application published under section 122(b) of this title may be made in *an application filed after the application is published* only if the claim is made before 1 year after the date on which the application is published.

35 U.S.C. §135(b)(2), emphasis added.

As can be seen from the italicized text quoted above, section 135(b)(2) applies only to applications filed after the publication of the application from which claims are copied. The present application was filed *before* the publication of U.S. Application Publication No. 2002/0037323, and therefore it is not subject to the provisions of section 135(b)(2). The Office also cites case law in apparent support of this rejection (*In re McGrew*, 120 F.3d 1236 (Fed. Cir. 1997); *In re Berger*, 61 USPQ2d 1523 (Fed. Cir. 2002); and *Berman v. Housey*, 63 USPQ2d 1023 (Fed. Cir. 2002)). None of these cases, however, addresses the issue of an applicant failing to copy claims from a published application. Rather, these cases deal with failure to copy claims from issued patents within the one-year period under 35 U.S.C. §135(b)(1) and are, therefore, inapposite in the present situation.

Applicant interpretation of the language in section 135(b)(2) finds support in the M.P.E.P., which after discussing the one-year period to copy claims from issued patents states:

Further, if the patent issued from an application which was published under 35 U.S.C. 122(b), note the one year from publication date limitation found in 35 U.S.C. 135(b)(2) *with respect to applications filed after the date of publication.*

M.P.E.P. § 2307, emphasis added.

Therefore, section 135(b) does not support this rejection and Applicant respectfully requests that this rejection be withdrawn.

IV. Claim objections

The Office objected to claim 66 allegedly "for failing to further limit the subject matter of a previous claim." Claim 66 has been deleted and therefore this objection is now moot.

V. Conclusion

Applicant respectfully requests that this Amendment under 37 C.F.R. § 1.116 be entered by the Office, placing claims 25-65 and 67-73 in condition for allowance.

Applicant submits that the proposed amendments of claims 62, 68, and 70 do not raise new issues or necessitate the undertaking of any additional search of the art by the Office, since all of the elements and their relationships claimed were either earlier claimed or inherent in the claims as examined. Therefore, this Amendment should allow for immediate action by the Office.

It is respectfully submitted that the entering of the Amendment would allow the Applicant to reply to the final rejections and place the application in condition for

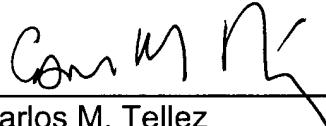
Patent Application No. 09/869,031
Attorney Docket No. 06478.1473

allowance. Applicant, therefore, requests the entry of this Amendment, the Office's reconsideration and reexamination of the application, and the timely allowance of the pending claims.

Please grant any extensions of time required to enter this response and charge any additional required fees to our deposit account 06-0916.

Respectfully submitted,

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